JUN 2 6 2001

K011321

510(k) Summary

1.0 Date Prepared

April 26, 2001

2.0 Submitter (Contact)

Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name:	XPS 3000 System
Common Name(s):	Electrical surgical shavers, electrical microresectors, mastoid drills, microdrill, ENT drills, handpieces and cutting blades, rasps and burs
Classification Name(s):	Drill, Surgical, ENT (Electric or pneumatic) including handpiece; ENT bur

4.0 Device Classification

Classification Name:	Drill, Surgical, ENT (Electric or pneumatic) including handpiece; ENT bur		
Procode:	77ERL	Class II	21 CFR § 874.4250
	77EQJ	Class II	21 CFR § 874.4140

5.0 Device Description

The XPS 3000 system consists of a power control console, footswitches, connection cables, and assorted handpieces to drive various burs, blades, drills, and rasps.

Revised
6/18/01

6.0 Indications for Use

The XPS 3000 system, microresector handpieces, and cutting accessories, are intended for the incision and removal of soft and hard tissue or bone in otorhinolaryngology, head and neck surgery including the surgical management of recurrent respiratory papillomatosis (RRP).

7.0 Substantial Equivalence

The proposed XPS 3000 system is substantially equivalent in operating principle, technology, overall design, function, and materials to the XPS system described in K002224 which includes indications for laryngeal lesion debulking, and tracheal procedures. Clinical evaluation and risk analysis reveal no new safety or efficacy issues in the surgical management of recurrent respiratory papillomatosis.

Characteristic	XPS 3000 Expanded Indications: RRP	XPS 3000 (K002224)
Intended Use / Indications for use	Cutting soft tissue and bone	Cutting soft tissue and bone
Magnum / Straightshot Microresector FWD / REV	Default: 6,000 RPM Max: 6,000 RPM	Default: 6,000 RPM Max: 6,000 RPM
Magnum / Straightshot Microresector Oscillation Speed	Default: 3,000 RPM Max: 3,000 RPM	Default: 3,000 RPM Max: 3,000 RPM
Magnum II Microresector FWD / REV	Default: 6,000 RPM Max: 15,000 RPM	Default: 6,000 RPM Max: 15,000 RPM
Magnum II Microresector Oscillation Speed	Default: 3,000 RPM Max: 5,000 RPM	Default: 3,000 RPM Max: 5,000 RPM
Steam autoclavable handpieces	Yes	Yes
Blade sizes (O.D.)	2.0 mm - 6mm	2.0 mm - 6mm
Direct patient contacting materials (Burs / Blades)	Stainless Steel and medical polymer	Stainless Steel and medical polymer
Blades / burs biocompatible	Yes	Yes
Perastaltic pumps	2 pumps, 1 for irrigation and 1 optional pump for handpiece cooling	2 pumps, 1 for irrigation and 1 optional pump for handpiece cooling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medtronic Xomed, Inc.
c/o Mr. Martin D. Sargent
Regulatory Affairs Manager
6743 Southpoint Dr. N.
Jacksonville, Florida 32216-0980

Re: K011321
Trade Name: XPS 3000 System
Regulation Name: 874.4250
Regulatory Class: II
Product Code: 77 ERL
Dated: April 26, 2001
Received: April 27, 2001

Dear Mr. Sargent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011321
Device Name: XPS 3000 System
Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011321

Prescription Use ✓ Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)